LIBRARY
SUPREME COURT

Office Supreme Court, U.S.
FILED
DEC 7 1962
JOHN F. DAVIS, CLERK

IN THE

Supreme Court of the United States

October Term, 1962

No. 643

NATURE FOOD CENTRES, INC., and HENRY K. ROSENBERGER and ANDREW G. ROSENBERGER,
Petitioners.

AGAINST

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

MILTON A. BASS,
SOLOMON H. FRIEND,
Counsel for Petitioners,
342 Madison Avenue,
New York 17, N. Y.

LODER APPEAL PRESS, INC., 41 VESEY STREET, NEW YORK, N. Y. WORth 2-0689

INDEX

	PAGE
Citations to Opinions Below	1
Jurisdiction	2
Questions Presented	2
Statutes Involved	3
Statement	3
Reasons for Granting the Writ	5
Conclusion	15
Appendix A	17
Appendix B	26

CASES CITED

Irons, V. E., Inc. v. United States, 244 F. 2d 34 (C. C. A. 1, 1957)	8
Kordel v. United States, 335 U. S. 345 (1948)	2, 6, 7
United States v. Cardiff, 344 U. S. 174	10
United States v. Dotterweich, 320 U. S. 277	11

PAGE

United States v. Urbuteit, 335 U. S. 355 (1948) ... 2, 6

United States v. Urbuteit, 336 U. S. 804 (1949) ... 2, 6, 7

United States v. 353 cases * * * Mountain Valley Mineral Water, 247 F. 2d 473 (C. C. A. 8, 1957) 8

STATUTES CITED

Federal Food, Drug and Cosmetic Act (21 U. S. C. 301, et seq.) 2, 3, 4, 5, 6, 7, 8, 10, 11, 15

21 CFR 1.106(a)(1) 2, 3

IN THE

Supreme Court of the United States

OCTOBER TERM, 1962

No. . . .

NATURE FOOD CENTRES, INC., and HENRY K. ROSENBERGER and ANDREW G. ROSENBERGER,

Petitioners,

AGAINST

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the First Circuit, entered in the above-entitled case on November 13, 1962.

Citations to Opinions Below

The opinion of the District Court is printed in Appendix A, *infra*, page 17, and is not officially reported. The opinion of the Court of Appeals is printed in Appendix A, *infra*, page 19, which is not yet officially reported.

Jurisdiction

The judgment of the Court of Appeals was entered on November 13, 1962 (Appendix A, *infra*, p. 25). The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

Questions Presented

1. Whether the Court of Appeals was in error in creating two different definitions for the term "labelling", depending upon the section of the Federal Food, Drug and Cosmetic Act in which it appears; where Congress has expressly set forth but one definition.

2. Whether the duality of definition for the term "labelling" created by the Court of Appeals, renders invalid various sections of the Federal Food, Drug and Cosmetic Act because of the resultant vagueness and indefiniteness.

3. Whether the definition for the term "labelling" created by the Court of Appeals is in conflict with the decisions of this Court in *Kordel* v. *United States*, 335 U. S. 345 (1948); *United States* v. *Urbuteit*, 335 U. S. 355 (1948), and *United States* v. *Urbuteit*, 336 U. S. 804 (1949).

4. Whether the standard laid down by the Court of Appeals for compliance with the requirements of Section 502(f)(1) and Regulation 1.106(a)(1), for the statement of conditions of intended use, is correct in a criminal case.

5. Whether the petitioners could be found guilty on all counts of the criminal information even under the standard applied by the Court of Appeals.

Statutes Involved

The statutory provisions involved are Sections 201(k), 201(m), 502(a), 502(d), 502(e), and 502(f)(1) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(k), 321(m), 352(a), 352(d), 352(e) and 352(f)(1)]. Also involved is the Regulation, 21 CFR 1.106(a)(1). They are printed in Appendix B, *infra*, page 26.

Statement

Petitioners are distributors of vitamin products and dietary food supplements throughout the United States. The government prosecuted the petitioners by an information containing thirteen counts.

All of the counts of the information raise in issue one question, as to whether various conditions which were referred to in certain oral lectures are also mentioned or referred to in any of the written or printed material which constitute labelling under the Federal Food, Drug and Cosmetic Act.

No charge has been made in the information that false or misleading claims were made for the products.

The entire case was submitted on a stipulation of facts. The shipments in issue constituted a single shipment in each instance from Boston, Massachusetts to Philadelphia, Pennsylvania or Chicago, Illinois, where part of the shipment was retained in a retail store and the remaining portion went to a lecture hall. It was further stipulated that one of the petitioners lectured for four days in Philadelphia and for four days in Chicago in a lecture hall in each city where the various products in issue were displayed and offered for sale together with the class notes and other literature. It was further stipu-

lated that the lectures were basically taken directly from the class notes.

The government contended that the class notes and other literature do not constitute labelling and further argued, in the alternative, that if the literature did constitute labelling, then five of the thirteen counts would still remain upon the ground that the class notes did not adequately state the conditions of intended use with respect to five of the thirteen counts.[1]

The District Court found the petitioners guilty on all thirteen counts. The District Court ruled that the class notes were labelling and further ruled that the references in the class notes and the lectures were vague, general, and sketchy, and therefore, did not comply with the statute.

The Court of Appeals affirmed the judgment of the District Court but, significantly, ruled completely opposite on the two findings made by the District Court. The Court of Appeals held that the class notes do not constitute labelling, where the question arises under Section 502(f)(1) as distinguished from 502(a) of the Act and further stated that the District Court possibly misspoke itself in its finding that there were vague and general references in both the lectures and the class notes. The completely opposite findings of the District Court and the Court of Appeals is of significance in view of the fact that the entire case was submitted on a stipulation of facts.

---

[1] In the District Court, the government admitted in its brief and in oral argument that eight counts would fall if the Court held that the class notes constitute labelling. The government denied that it had made such an admission, in the Court of Appeals, apparently because the District Court held that the class notes were labelling and then disregarded the government's admission in finding the petitioners guilty on all thirteen counts.

The District Court sentenced petitioner, Nature Food Centres, Inc. to pay a fine of $10,000; petitioner, Henry K. Rosenberger was sentenced to be imprisoned for a period of six months, execution of sentence suspended and petitioner placed on probation for a period of two years and to pay a fine of $5,000; and petitioner, Andrew G. Rosenberger was sentenced to be imprisoned for a period of six months, execution of sentence suspended and petitioner placed on probation for a period of two years and to pay a fine of $5,000.

Reasons for Granting the Writ

Petitioners submit that the creation of a duality of definition for the term "labelling", by the Court of Appeals, raises an important question of statutory construction which materially affects the entire Federal Food, Drug and Cosmetic Act. The Court of Appeals has ruled that the word "labelling" changes its definition when it moves from one section to another in the same statute. The term "labelling" is employed in numerous sections throughout the statute in laying down various requirements and creating criminal and civil liabilities. Congress has set forth but one definition for the term "labelling" in this statute. Significantly, Congress has also set forth a definition for the term "label" where Congress has desired to distinguish between two different types of literature, contemplated under the statute. It is respectfully submitted that this new construction of the statute, by the Court of Appeals, should be settled by this Court. Many actions have been brought under the specific section involved in the instant action and the new construction by the Court of Appeals materially affects the entire statute.

Petitioners further urge that the construction set forth by the Court of Appeals is in conflict with the prior decisions of this Court in *Kordel* v. *United States, supra*, and *United States* v. *Urbuteit, supra;* and in conflict with decisions in other cases which have followed the rulings of this Court.

Petitioners respectfully further urge that the new construction created by the Court of Appeals raises an important constitutional question as to whether numerous sections of the statute, as so construed, are rendered invalid for vagueness and indefiniteness. An individual cannot know which definition of the term "labelling" applies in each of the various sections of the statute, so that he cannot know what acts would constitute a criminal violation in each instance, nor what acts of compliance are required under each section.

The petitioners further urge that the construction by the Court of Appeals as to the standard required for compliance with Section 352(f)(1) is erroneous. A very strict and narrow construction of compliance has been applied by the Court of Appeals in imposing criminal liability, in a statute where intent is not an element of the crime.

Settlement of these questions involving both liberty and property is, therefore, in the public interest.

1. The Court of Appeals has ruled that a different kind of "labelling" is required under Section 502(f)(1) of the statute as distinguished from literature which would constitute "labelling" under Section 502(a) of the statute. This construction by the Court of Appeals is erroneous. The Court has, in effect, legislated rather than engaged in judicial construction or interpretation.

Congress has set forth only one definition for the term "labelling" as that term is used in numerous sections

throughout the statute. Section 201(m) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(m)] defines the term "labelling" as written, printed or graphic matter upon any article or "accompanying such article". This Court has heretofore interpreted the term "labelling" with specific reference to the phrase "accompanying such article" in *Kordel* v. *United States, supra*, and *United States* v. *Urbuteit, supra*. In both of these cases, the Court has held that the word "accompanying" as used in the statute does not mean physically present with the product. This Court has held that the controlling factors are whether the literature was designed for use in the distribution and sale of the product and whether it was so used. (See *United States* v. *Urbuteit*, 336 U. S. 804, at page 805 and *Kordel* v. *United States, supra*, at page 350.)

Thus, in *Kordel* v. *United States, supra*, it was held that various literature "accompanied" the products so as to constitute "labelling" under the statute. Some literature was displayed with the products, some literature was sold independently of the drugs, and some literature was mailed to customers by the vendors, including one instance where there was a separation of eighteen months between the shipment of the article and the printed material. This Court held that the fact that some of the booklets carried a selling price was immaterial, as they were part of the distribution program. It is thus apparent that literature constitutes "labelling" under the statutory definition even though there is no physical attachment and even if it is separately offered for sale and thus may never be seen or received by the consumer of the product. Literature will nevertheless constitute labelling where it is designed for use and is used in the distribution and sale of a product. The de-

cisions of this Court have been followed and applied in numerous other cases, including *United States* v. *353 cases* * * * *Mountain Valley Mineral Water*, 247 F. 2d 473 (C. C. A. 8, 1957) and *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34 (C. C. A. 1, 1957).

It is further significant that Congress has created a definition for the term "label" in Section 201(k) of the Act [21 U. S. C. 321(k)] which means written, printed or graphic material upon the immediate container of the article.

Where Congress wanted certain material to be on the label, present with the product, it so stated, as in Sections 21 U. S. C. 352(d) and (e) [Sections 502(d) and (e) of the Act]. In other sections such as Sections 352(a) and 352(f)(1) [Sections 502(a) and 502(f)(1) of the Act], Congress used the word "labelling" and not the word "label". If Congress had desired to have the information on the label or immediately present with the product as to the information required in 502(f)(1), then Congress would have so stated as it did in the various other sections herein referred to. Congress was very precise in using the word "label" in certain sections and the word "labelling" in others. There are not two different meanings to the word "labelling" in the various sections of the statute.

The Court of Appeals may believe that the requirements of 502(f)(1) should be contained in literature immediately present with the product when offered for sale. This belief or desire, however, cannot be effectuated by judicial interpretation, but is one which would require an amendment by Congress. The change herein attempted by the Court of Appeals is one which is legislative rather than judicial.

Significantly, the charge in the instant case is one of alleged misbranding when the products were introduced into and while in interstate commerce from Boston to Philadelphia and Chicago, respectively. The significance is the omission of any charge of misbranding while held for sale after shipment in interstate commerce. The shipment in each instance constituted a single shipment from Boston destined to Philadelphia or Chicago where part of the shipment was retained in the store and part at the lecture hall. The importance of this fact arises out of the bringing into effect and applying to said shipments the lectures, where the claimed intended uses are drawn from, and the attempt of the government to separate the portion of the shipment which ultimately ended up for sale at the lecture hall. Petitioners are not presently embarking upon a complete discussion of this legal issue. However, it is most significant that it was the very same persons who heard the lectures, and thus the intended uses, to whom were displayed, distributed or available for distribution the class notes and other literature with the products herein.

In the instant case, the class notes and other literature were printed by the petitioners and shipped from Boston to Philadelphia and Chicago. There was a common origin of the products and literature and a common destination of the products and literature at the lectures where the claimed uses were set forth and before the very same persons who heard them.

The literature was designed for use and was used by petitioners in the distribution and sale of the products herein. The literature was displayed with the products and distributed or available for distribution at the lecture halls where the eight specific lectures were given. It is these very lectures which constitute the basis or source of the conditions of intended use.

The criteria laid down by this Court whereby printed matter accompanies an article so as to constitute labelling therefor, are present in the instant case.

2. The Court of Appeals has now stated that the definition of "labelling" in Section 502(f)(1) of the statute is different from the definition of "labelling" in Section 502(a). This duality of definition of the word "labelling" renders numerous sections of the statute void for vagueness and indefiniteness. The word "labelling" and requirements relative thereto appear throughout the statute; with concomitant criminal liability for a failure of compliance.

In view of the decision of the Court of Appeals, we do not know which definition of "labelling" applies in each instance.[2]

A statute which forbids the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning, and differ as to its application, violates the first essential of due process of law.

As this Court said in *United States v. Cardiff*, 344 U. S. 174, 176, holding invalid for indefiniteness Section 704 of the Federal Food, Drug and Cosmetic Act (21 U. S. C. 374):

> "The vice of vagueness in criminal statutes is the treachery they conceal either in determining

[2] See, for example, Section 403(k) which provides that a food shall be deemed to be misbranded unless certain specified information is set forth in the labelling. At this moment we do not know which definition of labelling applies and the problem is further confused when one refers to Section 403(j) which sets forth certain other information which must be upon the *label*. Other sections of the statute which refer to labelling include Section 201(n), 403(a), 403(k), 502(a), 502(f), 505(b), 602(a) and 602(c).

what persons are included or what acts are prohibited. Words which are vague and fluid (Cf. United States v. L. Cohen Grocery Co. 255 U. S. 81, 65 L. ed. 516, 41 S. Ct. 298, 14 ALR 1045) may be as much of a trap for the innocent as the ancient laws of Caligula."

In the instant case, the decision of the Court of Appeals has created vagueness and indefiniteness with respect to numerous acts prohibited under the Federal Food, Drug and Cosmetic Act. The word "labelling" has been changed to a fluid state.

The wrong created by the decision of the Court of Appeals is magnified by the fact that wilfullness is not an element of the crime under the Federal Food, Drug and Cosmetic Act. The penalties of the law may be imposed upon one wholly innocent of knowledge or intent to achieve a purpose proscribed by the statute (*United States* v. *Dotterweich*, 320 U. S. 277).

There would thus appear to be no proper permissible latitude for indefiniteness, herein, where intent to achieve a proscribed purpose is not an element of the crime.

3. The Court of Appeals held that the contents of the class notes fall short of the lectures and thereupon submitted three examples which refer to three counts of the information. Petitioners respectfully submit that even if the strict construction laid down by the Court of Appeals were to be applied in a criminal case, there would still, at a minimum, be eight counts which must be dismissed. The government itself did not question or dispute this fact in the District Court with respect to sixty-one conditions of the seventy-three listed in the information.[3] The sixty-one undisputed conditions would require

[3] See Footnote 1, *supra*.

the aforesaid dismissal of at least eight counts of the information. Illustrative of the fact that the great majority of the conditions are clearly set forth in the class notes and that no question of construction exists, are the following:

a. One of the conditions referred to is that of heart disease and its reference to the Vitamin E (Super E) product. Exhibit 2 (App. 58a) at the bottom of page 4 and top of page 5, clearly states:

> "The value of Vitamin E in heart disease has been demonstrated. * * * the ability of Vitamin E * * * to treat and prevent heart diseases of all types * * *."

There is a further discussion of the use and value of Vitamin E in the treatment of heart disease on those pages and also there may be found a reference to this same fact in Exhibit 1, (App. 56a) at the bottom of page 10 where it states that Vitamin E is needed for a healthy heart.

b. Another claim involved in the information is that relating to healthy skin and Vitamin B (B Amino Complex Product). In Exhibit 1 (App. 56a) page 9, there is a discussion of Vitamin B complex which says that niacin, which is listed under the group of ingredients of the Vitamin B complex "is necessary for healthy skin".

These examples may be multiplied and as previously indicated herein, were not the subject of dispute in the District Court where the government was compelled to concede that if the literature was held to be labelling there could be no question relative to the listing of at least sixty-one of the conditions.

With respect to the three counts involved in the three conditions referred to by the Court of Appeals, petition-

ers respectfully submit that the standard laid down by the Court of Appeals in a criminal case for such compliance is too strict and too narrow to support a criminal conviction.

Thus, the Court of Appeals states that the lecture discussed the restoration of the original color of the hair by the use of petitioners' Vitamin B product called Hemo-Glo. In the class notes, Vitamin B complex, is discussed as helping to prevent graying of hair and in retaining normal hair coloring. The Court draws a very fine line of distinction between the words retaining normal hair coloring, preventing graying of the hair and restoring original color.

The Court also discusses the loss of smell referred to in Count Five of the information. The lecture which discusses the loss of smell clearly states in Exhibit 20, at the bottom of page 7 (App. 91a):

> "Lost part of hearing and smell after a very bad cold * * *."

The loss of smell was thus discussed as a symptom related to a cold or caused by a cold. In the class notes, petitioner discussed this subject in Exhibit 3a (App. 60a) on pages 53 and 54, and also sets forth further discussion of this kind in Exhibit 2 (App. 58a) beginning on page 21 which discusses the entire question of colds and the prevention of colds. The statement of conditions most certainly should not be one of isolating a single word out of context from a complete discussion of a subject. In both instances, we have a discussion of colds and the reference carefully extracted by the Court is as to a symptom which the lecture clearly referred to as relating to or being caused by a cold. Were we to carry forward and apply the standard laid down by the Court of Ap-

peals, we could find a variance, and thus a criminal violation of the statute, if in one place the petitioner said that you could treat colds and discussed somewhere in his statement having had *sniffles* when he had a cold, whereas, in the other literature he merely discussed colds without the one word *sniffles*.

It is submitted that the purpose and intent of the statute is not to ensnare and trap the businessman for failure to repeat a word or phrase. The statute requires a statement of the conditions for use of the product and compliance should not require fine lines of language interpretations.[4]

The statute and regulations require that there be a statement of the conditions of intended use. It is thus apparent that the question involves two factors. The first factor is the source of the intended use which, in the present case, is the lectures, and the second factor is the labelling material which, in the instant case, is the class notes and other circulars. Petitioners submit that there has been compliance with the statutory requirements. The conditions of use which are discussed in the lectures are set forth in the literature. Significantly, it was even stipulated between the parties, in paragraph numbered 54 of the stipulation of facts, that the material for the lectures was "basically taken directly from the class notes" (App. 44a). This stipulation of fact is particularly relevant in a criminal case where the government must prove its charges beyond a reasonable doubt and must thus prove a variance between the lectures and the class notes which is one of substance and not microscopic differences.

---

[4] With respect to the reference to lung conditions, the Court of Appeals apparently overlooked the statement in Exhibit 3a (App. 60a) Page 12 which refers to the lungs and the accumulation of extracellular fluids in the lungs in the second paragraph from the bottom of that page.

Petitioners respectfully submit that this Court should rule upon and settle this question as to the standard of compliance required, in a criminal action, under Section 502(f)(1) of the statute.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

MILTON A. BASS,
SOLOMON H. FRIEND,
Counsel for Petitioners.

Dated: December 6, 1962.

APPENDIX A

AMENDED OPINION

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

Criminal Action No. 59-257-S

June 8, 1962

UNITED STATES OF AMERICA,

v.

NATURE FOOD CENTRES, INC., a corporation, and HENRY K. ROSENBERGER, and ANDREW G. ROSENBERGER, individuals,

SWEENEY, CH. J. This criminal case was submitted to the Court on a stipulation of facts signed by all of the parties together with certain exhibits in the nature of the articles offered for sale and with lectures and class notes and other literature provided by the defendants. There are 13 counts in the information, and a finding of guilty is made as to each of the defendants in all of the counts.

I find from the stipulated facts that the articles shipped in interstate commerce were drugs within the meaning of the statute. I find that each was intended to be used for the treatment of one or more diseases. I find that each of the defendants violated 21 U. S. C. 352 in that the labeling (including the lectures, class notes and other

information disseminated at the lectures) did not bear adequate directions for the use of the drugs offered which were, therefore, within the meaning of the statute, misbranded. The legislation covering this offense must be given a liberal interpretation to effectuate its high purpose of protecting unwary consumers in vital matters of health. The very vague, general and sketchy references to the drugs in question in the lectures and in the class notes do not comply with this statute's direction for "adequate directions for use."

The defendants are ordered to appear before this Court for sentencing on Tuesday, June 19, 1962, at 11:30 A.M.

Appendix A

OPINION

UNITED STATES COURT OF APPEALS

FOR THE FIRST CIRCUIT

No. 6031.

NATURE FOOD CENTRES, INC., *et al.*,
Defendants-Appellants.

v.

UNITED STATES OF AMERICA,
Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Before WOODBURY, Chief Judge, and HARTIGAN and ALDRICH, Circuit Judges.

Milton A. Bass, with whom Bass & Friend was on brief, for appellants.

William W. Goodrich, Assistant General Counsel, with whom W. Arthur Garrity, Jr., United States Attorney, Walter E. Byerley, Attorney, and Stanislaw R. J. Suchecki, Assistant U. S. Attorney, were on brief, for appellee.

OPINION OF THE COURT

November 13, 1962

ALDRICH, Circuit Judge. The defendants were charged in a 13-count information with introducing into interstate

commerce certain drugs misbranded within the meaning of 21 U.S.C. §352(f)(1), "in that [the] labeling failed to bear adequate directions for use in that the labeling of said drug failed to state the purposes, conditions, and diseases for which said drug was intended . . . ." The statutory language requires that the "labeling bears (1) adequate directions for use . . . .". In addition, the statute provides for the issuance of regulations. 21 U.S.C. §371 (a). The pertinent, applicable[1] regulation is as follows:

> "Statements of all conditions, purposes or uses for which such drug or device is intended, including conditions, purposes or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising . . . ." 21 C.F.R. §1.106(a)(1) (1955)

The case was tried to the court without jury on a stipulation of facts and exhibits. The court found the defendants guilty on all counts and they appeal.

The defendants complain at the outset of the court's findings of fact as being inconsistent with the government's charge, and allege that they require a dismissal. The findings may be not altogether clear, but the defendants' interpretation is unwarranted.[2] Furthermore,

---

[1] Defendants, properly, do not question the validity of this regulation. *Colgrove* v. *United States*, 9 Cir., 1949, 176 F. 2d 614, *cert. den.* 338 U. S. 911; *cf. V. E. Irons, Inc.* v. *United States*, 1 Cir., 1957, 244 F. 2d 34, 44, *cert. den.* 354 U. S. 923.

[2] The court said, "The very vague, general and sketchy references to the drugs in question in the lectures and in the class notes do not comply . . . ." Possibly the court misspoke itself, because nothing could be less vague than the references in the lectures (as distinguished from the class notes) to the defendants' products. It is true that in many instances the benefits were vaguely expressed. However, in others they were not.

since all the facts were stipulated, we must regard the court's error, if any, on a subsidiary matter as not prejudicial. Defendants concede in their brief, although with perhaps some other matters in mind, "The stipulated facts are before this Court. Appellants agree with appellee that this Court of Appeals can examine and evaluate the evidence in precisely the same manner as the District Court did." We pass, therefore, to the merits.

Each count alleges, and the stipulation shows, that defendants shipped certain bottles containing tablets or capsules from Massachusetts to their place of business in Philadelphia, or Chicago, and that the labels on said bottles bore a name, such as Colex, C-Aminos, Hemo-Glo, B-Amino-Complex, GL-12, and the statement that it was a "dietary supplement" containing three to fourteen or more specified ingredients. The stipulation further shows that said products were offered for sale throughout the month of April 1958, at defendants' said places of business, and for three days near the end of the month at a lecture hall elsewhere in each city, where defendants gave a series of lectures. At each lecture there were available, at $1.50 each,[3] so-called "Class Notes on Health and Nutrition" relating to the lecture for the day. These notes were not available at defendants' said places of business. It is the government's position that the labels on the bottles failed to show the "purposes or uses" for which the drugs were "intended;" that the defendants did have various purposes, as disclosed by the lectures; and hence that the drugs were "misbranded."

[3] This statement as to availability and price is over-favorable to the defendants.

Appendix A

The defendants do not seriously contend that their products are not drugs within the act. See *United States v. Hohensee*, 3 Cir., 1957, 243 F.2d 367, *cert. den.*, 353 U.S. 976. Their position with respect to purchasers at their places of business who did not know of the lectures was that as to them they did not have the purposes the lectures disclosed, so that further "labeling" was not needed. "[T]here is not a scintilla of evidence that the product shipped to the stores was intended for any use other than that which appeared on its label—that is, as a dietary supplement." This contention is scarcely realistic. It can hardly be thought that in offering such esoteric products as Isoleucine, Methionine and Tryptophane, not to mention Lecithin and Glutamic Acid which, among others, were described on the bottle as "Need in human nutrition not established," defendants had no special purposes in mind. The regulations, *supra*, cover this matter precisely by permitting reference to "oral, written, printed, or graphic advertising." The government properly introduced the lectures, transcribed by a government agent who had paid the entrance fee, as evidence of defendants' intentions. *V. E. Irons, Inc.* v. *United States*, 1 Cir., 1957, 244 F.2d 34, 44, *cert. den.* 354 U.S. 923; *United States* v. *Hohensee*, *supra*. In them the defendants made fulsome claims as to the preventative and curative qualities of their various products.

Defendants say, alternatively, that the class notes repeated "coextensively" what was said in the lectures, and accordingly, by disclosing these same purposes, satisfied the statutory requirements of "labeling." This contention cannot be supported. In the first place, the contents of the notes fell far short of the lectures. In the lectures all of the products were mentioned by name.

Appendix A

In the notes reference was made only to various substances. Even if, which we may question, identification by ingredients was sufficient, the claims or purposes stated in the lectures and in the notes were substantially different. For example, in one of the lectures defendants represented that "[g]ray hair can be restored to its original color by . . . using Hemo-Glo." As allegedly "coextensive," defendants point to the following statements in the notes, "Vitamin . . . B-Complex, helps to prevent the graying of hair . . . . Para amino benzoic acid is also valuable for the prevention of gray hair . . . . Folic acid . . . also plays a part in retaining normal hair coloring . . . ." We suggest that "helping" prevent, and restoring, are manifestly different.

Again, in a lecture defendants represented that "C-Aminos tablets . . . would be ideal for anyone suffering from a lung condition." The only reference we discover in the notes to any lung curative feature of defendants' products is that pulmonary edema resulting from congestive heart failure may sometimes be "got rid of" by "diuretic drugs." Such a case is somewhat less broad than "anyone suffering from a lung condition."

As a further example, defendants, in a lecture, after referring to a case of a man who "[l]ost part of . . . smell after a very bad cold four years ago," said, "Lots of B-Complex factors and protein could probably be most helpful for this condition." The "coextensive" portion of the notes to which their brief refers us states that B Complex (a disclosed ingredient in one of their products) is helpful in the prevention of colds. Defendants add in their brief (without evidentiary support, or citation to the notes) that a bad cold may leave one with a partial

loss of smell. It is difficult for us to think how defendants can possibly believe this is equivalency.

Secondly, the notes would not satisfy the requirements of labeling even if they repeated the lectures verbatim. It is true that a "labeling," as distinguished from a "label," need not be physically attached to the container. It is enough if it accompanies it. 21 U.S.C. §321(m). *Kordel* v. *United States*, 1948, 335 U.S. 345; *V. E. Irons, Inc.* v. *United States*, *supra*; *Drown* v. *United States*, 9 Cir., 1952, 198 F.2d 999, *cert. den.* 344 U.S. 920. But although by "accompanying" documents a defendant may incur liability for false labeling even though they do not accompany all the products, this does not mean that independent documents can satisfy affirmative labeling obligations with respect to those products they do not accompany. *Alberty Food Products Co.* v. *United States*, 9 Cir., 1950, 185 F.2d 321. Some of defendants' products were destined for sale at the stores, where the notes were not available. Even the documents at the lecture halls were obtainable only upon the payment of an additional price. The obligation to brand products is not met by a course of conduct which will result in manifest lack of fulfillment.

Defendants make a number of other contentions which we refrain from commenting upon.

Judgment will be entered affirming the judgments of the District Court.

Appendix A

JUDGMENT

UNITED STATES COURT OF APPEALS

FOR THE FIRST CIRCUIT

No. 6031.

NATURE FOOD CENTRES, INC., *et al.*,
Defendants-Appellants,

v.

UNITED STATES OF AMERICA,
Appellee.

JUDGMENT

November 13, 1962

This cause came on to be heard on appeal from the United States District Court for the District of Massachusetts, and was argued by counsel.

Upon consideration whereof, It is now here ordered, adjudged and decreed as follows: The judgment of the District Court is affirmed.

By the Court:
s/ ROGER A. STINCHFIELD,
Clerk.

[cc. Messrs. Goodrich and Bass.]

Thereafter, on November 26, 1962, mandate was stayed until further order of the Court of Appeals for the First Circuit.

APPENDIX B

STATUTES

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U.S.C. 301, *et seq.*), provides in pertinent part:

SEC. 201(k)

The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper [21 U.S.C. 321 (k)].

SEC. 201(m)

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article [21 U.S.C. 321(m)].

SEC. 502

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular [21 U.S.C. 352(a)].

* * * * *

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming" [21 U.S.C. 352(d)].

(e) If it is a drug and is not designated solely by name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary [21 U.S.C. 352(e)].

(f) Unless its labeling bears (1) adequate directions for use [21 U.S.C. 352(f)(1)].

Appendix B

REGULATION, SEC. 1.106(a)(1)

Drugs and devices; directions for use—(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner [21 CFR 1.106(a)(1)].

INDEX

	Page
Opinions below	1
Jurisdiction	1
Question presented	2
Statute and regulation involved	2
Statement	4
Argument	7
Conclusion	12

CITATIONS

Cases:

Alberty Food Products Co. v. *United States*, 185 F. 2d 321 11

Alberty Food Products v. *United States*, 194 F. 2d 463 11

Colgrove v. *United States*, 176 F. 2d 614, certiorari denied, 338 U.S. 911 9

Kordel v. *United States*, 335 U.S. 345 10

United States v. *Alberty Food Products*, 98 F. Supp. 23, affirmed, 194 F. 2d 463 9

United States v. *Various Quantities of Articles of Drug*, 83 F. Supp. 882 11

United States v. *Urbuteit*, 335 U.S. 355 10

United States v. *Urbuteit*, 336 U.S. 804 10

V. E. Irons, Inc. v. *United States*, 244 F. 2d 34, certiorari denied, 354 U.S. 923 9

Statute and regulation:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.*:

Section 201 2

Section 201(e) 2

Section 201(m) 2

Section 301 ..... 2, 4

Section 301(a) 2

Section 303 ..... 3, 4

Section 502 ..... 3, 7, 11

Section 502(f)(1) 3, 4

21 C.F.R. 1.106(a) 3, 9

671420—6*

In the Supreme Court of the United States

OCTOBER TERM, 1962

No. 643

NATURE FOOD CENTRES, INC., HENRY F. ROSENBERGER, AND ANDREW G. ROSENBERGER, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinions of the court of appeals (Pet. 19–24) and the district court (Pet. 17–18) are not yet reported.

JURISDICTION

The judgment of the court of appeals was entered on November 13, 1962 (Pet. 25). The petition for a writ of certiorari was filed on December 7, 1962. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Section 352 of Title 21 provides that a drug is misbranded unless its labeling includes "adequate directions for use." The question presented is whether this provision is satisfied by "class notes" of a health food lecturer, when the notes did not even mention the drugs by name, but referred generally to the claimed usefulness of components of the drugs, when the lecturer went further than the notes in making oral claims for the drugs, and when the notes frequently did not accompany the drugs at the time they were sold.

STATUTE AND REGULATION INVOLVED

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.*, provides in pertinent part:

Section 201 [21 U.S.C. 321]:

For the purposes of this Act—

* * * * *

(e) The term "person" includes individual, partnership, corporation, and association.

* * * * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

* * * * *

Section 301 [21 U.S.C. 331]:

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is * * * misbranded.

* * * * *

Section 303 [21 U.S.C. 333]:

(a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; * * *.

* * * * *

Section 502 [21 U.S.C. 352]:

A drug or device shall be deemed to be misbranded—

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; * * *.

21 CFR 1.106(a) provides in pertinent part:

(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising * * *.

* * * * *

STATEMENT

An information filed in the District Court for the District of Massachusetts under Sections 301 and 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 and 333) alleged in thirteen counts that petitioners, Nature Food Centres, Inc., and two of its employees, had caused the illegal shipment in interstate commerce of drugs which were misbranded in violation of Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1)) (R. 8a–25a).[1] The information alleged that the misbranding consisted of the failure of the drugs to bear labeling providing adequate directions for use in that it did not state the diseases, purposes, and conditions for which the drugs were actually intended. The seven drugs involved were Colex (Counts 1 and 12) (R. 9a, 23a), C-Aminos (Counts 2 and 11) (R. 10a, 22a), Safflower Oil Capsules (Counts 3 and 13) (R. 11–12a, 24a), Hemo-Glo (Counts 4 and 9) (R. 13a, 19a), B-Amino-Complex (Count 5) (R. 14a), Super E Plus (Counts 6 and 8) (R. 15a, 18a), and GL–12 (Counts 7 and 10) (R. 17a, 21a).

The case was submitted to the trial court on stipulated facts and exhibits (R. 27a–46a). The drugs at issue were labeled as "dietary supplements" supplying various proportions of the vitamins, minerals, proteins, amino acids, and other substances needed for an adequate diet. As to some of the ingredients, such as isolencine, methionine, tryptophane, lecithin, and glutamic acid, the labeling stated "need in human

[1] "R." refers to the appendix to appellants' brief in the court of appeals. "R.A." refers to the appendix to appellee's brief in that court.

nutrition not established." The labels (Ex. 10a–16b) made no mention of any medical value for any of the products.[2]

Proof that the articles were intended for use as drugs was established by evidence of the claims made in oral lectures to promote their sale given by petitioner Andrew Rosenberger in principal cities where Nature Food had branch health food stores. The mode of operation (see R. 40a–42a) was to announce a free lecture and an offer of a free gift to anyone who attended (Ex. 6 and 7, R. 67a and 69a). Persons attending were invited to sign up for three more lectures, for which an admission fee was charged. So-called class notes (Ex. 1, 2, and 3a, R. 57a, 59a, 61a) were sold at these lectures, either as a part of the admission fee or for an extra fee (Stip. 47(B)(3)(c) and (d), R. 41a), but the notes were not made available in the stores where the products were regularly offered for sale (Ex. 20, pp. 59–60, R.A. 101a). The class notes consisted of lengthy discussions of parts of the body, various diseases, the importance of diet to health, the impossibility of obtaining from normal food the nutrients that are needed for good health, the part played by poor soil, fertilization, the use of sprays, and processing of food in reducing the nutritive value of ordinary foods, and the role of natural

[2] For example, the label for Safflower Oil, which is typical, stated (Ex. 12b):

Safflower Oil Capsules—

A pleasant source of unsaturated fatty acids as supplied by safflower oil and Vitamin B6, for use as a dietary supplement in deficiencies of essential fats.

vitamins, natural minerals, lipotropic agents, protein, barbados molasses, tortula yeast, millet, and other unique foods in preventing and treating diseases. The class notes did not refer specifically to any of the drugs involved in this case.

In the lectures themselves, the Nature Food products were identified by name for use in the treatment of various diseases and symptoms.[3] For example, Safflower Oil, which, on the label, was identified as a dietary supplement was, according to the information presented in the health lectures, for use in the prevention of coronary thrombosis, heart attacks, and arteriosclerosis (Ex. 17, p. 36, R.A. 76a; Ex. 18, p. 35, R.A. 79a; Ex. 19, p. 18, R.A. 83a; Ex. 21, pp. 20–21, R.A. 103a–104a; Ex. 23, p. 12, R.A. 109a). Other drugs were similarly labelled and similarly described in the lectures as intended for the treatment of serious diseases.

The trial judge found petitioners guilty, holding that the class notes constituted labeling, but that they did not comply with the statute's requirement of providing adequate directions for use (Pet. 17–18). The corporation was fined $10,000, and the individual petitioners were each fined $5,000 and sentenced to imprisonment for six months. The sentences were suspended in favor of probation for two years (R. 48a–51a).

---

[3] Agents of the Food and Drug Administration attended the lectures and recorded the claims made for the product. Pertinent excerpts from the lectures were included in the government's appendix in the court below (R.A. 75a–116a). Copies of the lecture transcripts are filed with the court of appeals.

The court of appeals affirmed the conviction, holding that the references in the class notes did not satisfy the statutory command, both because they did not identify the drugs to which the claims were directed and because the directions for use in the notes fell far short of the oral claims made for the drugs in the lectures (Pet. 19–24). The opinion also stated, that, even if the directions for use in the notes had been adequate, they could not constitute labeling for the drugs sold in the Nature Food stores without accompanying notes.

ARGUMENT

Petitioners concede that the labelling on the drugs themselves did not constitute "adequate directions for use" as required by 21 U.S.C. 352. The only issue in this case, therefore, is whether the "class notes" which were available at lectures and intended to promote sale of the drugs constituted adequate labelling. We submit that these notes were not adequate for two separate reasons. First, the class notes, even if assumed to constitute labelling, were not adequate labelling both because they did not mention or identify the drugs and because they gave directions for use which fell short of the oral claims made to promote sales.[4] Second, the class notes could not constitute labelling as to the store sales where the notes did not accompany the drugs and were not associated with their sales. Both issues are essentially factual. We sub-

[4] Petitioners state (Pet. 4, note 1) that if the class notes constituted labelling, the government conceded in the district court that they could not be convicted on eight of the thirteen counts. No such concession, however, was made.

mit that the court of appeals properly held that petitioners' conviction was adequately supported by the evidence and that this determination does not call for further review.

1. The class notes made no mention at all of any of the drugs which Nature Foods sold. They did, however, describe the value and use of various substances which were included in the drugs. The inadequacy of this description in telling the purchaser of the use of the drugs themselves may be easily illustrated. C-Aminos, which is prepared from rose hips, was claimed by the lecturer to be effective in treating gouty arthritis (R.A. 75a, 102a). Petitioner argued in the trial court that the class notes provided adequate directions for this use in a full chapter of discussion on arthritis (Ex. 1, p. 27, R. 57a).[5] That chapter, however, states that arthritis is treated by drastic diet changes—by replacing meat and eggs with cottage cheese and related foods. There is no mention of C-Aminos (Ex. 1, p. 29). A reader trying to select a drug on the basis of the discussion would likely purchase B-Aminos or Hemo-Glo, which contain B-complex vitamins, not C-Aminos which contains Vitamin C and Amino-Acids.

Similarly, the lecturer claimed that B-Amino-Complex is to be used for a healthy skin. Petitioners rely (Pet. 12–13) for directions as to this use on a discussion of Vitamin B complex in the class notes, stating that niacin, which is listed under the ingredients of Vitamin B complex, is necessary for healthy

[5] Exhibit 1 was not even available for sale at the lectures (R. 42a; R.A. 78a–79a).

skin (Ex. 1, p. 9). However, here again, while the class notes discuss the B-group vitamins in relation to various conditions, they do not name specific products in relation to these conditions. Consequently, a consumer would be faced with a very real problem, if he should try to use the class notes as "directions for use." Both B-Amino Complex and Hemo-Glo contain the B-complex vitamins referred to in the class notes and the language in the class notes is as applicable to one as to the other. Such ambiguity is not the clear, understandable statement of intended uses required to comply with the statute's mandatory "adequate directions for use."

2. The regulations, 21 C.F.R. 1.106(a), *supra*, p. 3, provide that " 'adequate directions for use' means directions under which the layman can use a drug or device safely and for the purpose for which it is intended. Directions for use may be inadequate because * * * of omission * * * of (1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral * * * advertising * * *." This regulation, which spells out the natural meaning of the statute, has been upheld in several cases (see, *e.g.*, *United States* v. *Alberty Food Products*, 98 F. Supp. 23 (S.D. Cal.), affirmed, 194 F. 2d 463 (C.A. 9); *Colgrove* v. *United States*, 176 F. 2d 614 (C.A. 9), certiorari denied, 338 U.S. 911; *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34 (C.A. 1), certiorari denied, 354 U.S. 923) and is not challenged here.

Petitioners' class notes clearly did not satisfy the statute as elaborated in the regulations. As the court of appeals held (Pet. 23), "the claims or purposes stated in the lectures and in the notes were substantially different." This determination is supported by the three examples which the court of appeals gave in its opinion (Pet. 23–24).

3. The court of appeals stated (Pet. 24) that "although by 'accompanying' documents a defendant may incur liability for false labeling even though they do not accompany all the products, this does not mean that independent documents can satisfy affirmative labeling obligations with respect to those products they do not accompany." Petitioners argue that this aspect of the decision gives the term "labeling" a dual meaning and thereby introduces unconstitutional uncertainty into the statute.

There has, however, been no holding giving the term "labeling" different meanings. Documents which accompany some articles may be false in their relationship to those articles even though they are obviously not false as to other articles which they do not accompany. On the other hand, documents may constitute adequate labeling as to articles which they accompany, but they obviously cannot be adequate as to articles which they do not accompany.

Petitioners rely on *Kordel* v. *United States*, 335 U.S. 345, *United States* v. *Urbuteit*, 335 U.S. 355, and *United States* v. *Urbuteit*, 336 U.S. 804. Those cases hold merely that documents may accompany an article even if they are not physically attached or are not in the same mail as long as they "were nonetheless

interdependent [or] parts of an integrated distribution program." 335 U.S. at 350. But independent documents far removed from the point of sale cannot satisfy the affirmative requirement that labeling for drugs bear adequate directions for use. A drug is misbranded for failure to bear adequate directions for use unless there is labeling material closely enough associated with the drug at the point of its sale to enable the prospective purchasers to learn "whether the drug is one which is prescribed, recommended, or suggested for their particular form of * * * ailment." This was the holding in *Alberty Food Products Co.* v. *United States,* 185 F. 2d 321, 325 (C.A. 9), which was followed by the court below. See also *Alberty Food Products* v. *United States,* 194 F. 2d 463 (C.A. 9). In this case, the class notes could not constitute adequate labeling since they were available only to those who bought them at the lectures and were never available in the retail stores where the products were merchandised (Ex. 20, pp. 59–60, R.A. 101a).

There is no unconstitutional uncertainty introduced into the statute by the holding that the class notes were not sufficient to provide adequate directions for use. Honest enterprise can readily meet the statutory requirements by including in the promotional material used at the point of sale the same claims that are used in advertising, written or oral, to promote the sale.[6]

---

[6] For a good discussion of the purpose of 21 U.S.C. 352(f)(1) in promoting honest enterprise, see *United States* v. *Various Quantities of Articles of Drug*, 83 F. Supp. 882, 885 (D.C. D.C.).

CONCLUSION

For the foregoing reasons we respectfully submit that the petition for a writ of certiorari should be denied.

ARCHIBALD COX,
Solicitor General.
HERBERT J. MILLER, JR.,
Assistant Attorney General.
BEATRICE ROSENBERG,
Attorney.

WILLIAM W. GOODRICH,
Assistant General Counsel,
WALTER E. BYERLEY,
Attorney,
Department of Health, Education, and Welfare.

JANUARY 1963.

U.S. GOVERNMENT PRINTING OFFICE:1963

SUPREME COURT, U. S.

Office-Supreme Court, U.S.
FILED
JAN 15 1963
JOHN F. DAVIS, CLERK

IN THE

Supreme Court of the United States

October Term, 1962

No. 643

NATURE FOOD CENTRES, INC., and HENRY K. ROSENBERGER and ANDREW G. ROSENBERGER,

Petitioners,

AGAINST

UNITED STATES OF AMERICA,

Respondent.

PETITIONERS' REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

MILTON A. BASS,
SOLOMON H. FRIEND,
Counsel for Petitioners,
342 Madison Avenue,
New York 17, N. Y.

LOOMIS APPEAL PRESS, INC., 41 VESEY STREET, NEW YORK, N. Y. WORth 2-0689

IN THE

Supreme Court of the United States

OCTOBER TERM, 1962

No. 643

NATURE FOOD CENTRES, INC., and HENRY K. ROSENBERGER and ANDREW G. ROSENBERGER,

Petitioners.

AGAINST

UNITED STATES OF AMERICA,

Respondent.

PETITIONERS' REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

The petition, heretofore filed, clearly sets forth the questions presented which warrant review. The Government has failed to respond to these questions and has instead created an irrelevant premise for the purpose of extensive argument.

The Government's brief (on page 2 thereof) attempts to combine three statements into one purported question presented. This question, however, is not the question presented for review. Thus, the Government states in its question presented that the notes did not mention the drugs by name in the class notes. The issue in this case

is not whether the drugs are mentioned by trade name in the labeling material. The issue presented in this case is whether the disease conditions, and not the drug names, are mentioned by name in the labeling material. It is further submitted that separate and apart from its non-applicability in this case, it is also irrelevant under the Federal Food, Drug and Cosmetic Act. Literature has been held to constitute labeling for a product, under the Act, which makes no mention whatsoever of the product by trade name, but rather by its ingredients or components. See *United States* v. *8 Cartons, etc.*, 97 F. Supp. 313 and 103 F. Supp. 626 (W. D. N. Y., 1951) where a book was held to constitute labeling for a product wherein the product is nowhere mentioned by its trade name, but solely by a reference to the ingredient. This has similarly been true in other cases involving literature and books, including *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34 (C. C. A. 1, 1957), and cases involving Dr. Jarvis' book titled "Folk Medicine".

It may be noted that there is a more precise designation of the product in the instant case than that which was present in other cases herein cited such as the *Irons* case, *supra*, wherein various newsletters merely discussed nutrition and vitamins in general terms whereas in the instant case, the products are specifically identified by the principal ingredient such as Vitamin B or Vitamin C, in the labeling notes. The Government has set forth and created this nonexistent issue and thereupon proceeds to argue its self-created question on pages 6 and 7 of its brief.

The same omnibus question presented also incorporates another irrelevant statement wherein it states, at the end of the paragraph, that the notes frequently did not accompany the drugs at the time they were sold. This ques-

tion is similarly not the issue presented herein. The literature does not have to be with the product at the time that it is sold to constitute labeling for the product. That is precisely what this Court said in *Kordel* v. *United States*, 335 U. S. 345 (1948), *United States* v. *Urbuteit*, 335 U. S. 355 (1948), and *United States* v. *Urbuteit*, 336 U. S. 804 (1949). In the *Kordel* case, *supra*, the argument was made that the literature must be with the product as to time and physical proximity to satisfy the statutory requirement of "accompanying". This Court did not accept this requirement and ruled that the statutory "accompanying" between the product and the literature could even be eighteen months apart so long as the literature was used as part of an interdependent distribution program in the marketing of the product.

The Government's brief contains extended argument premised upon these questions which are neither material nor relevant to the review sought by the petitioners. Thus, on pages 5 and 7 of the Government's brief, we find continued references to this alleged issue of the literature not being at the store. It is further significant that none of the counts in the information involve an alleged misbranding while the products were held for sale at the store, but rather allege misbranding when the products were introduced into and while in interstate commerce.

On page 7 of its brief, the Government states, in the first sentence under its heading of "Argument", that petitioners concede that the labeling on the drugs do not constitute adequate directions for use. No such concession was made. The Government has incorrectly used the term *labeling* as distinguished from the term *label*. As discussed in the petition herein, this distinction is a significant factor in this case, as Congress has clearly and spe-

cifically distinguished the term *labeling* from the term *label*, both as to definition and requirements under the Act.

The Government further argues, on the bottom of page 7 of its brief, that the issue of whether the class notes constitute labeling under the Statute is essentially a factual question. This is not true. The definition of labeling and more specifically the interpretation of the word *accompanying* in the statutory definition, is a question of law. This Court most certainly considered it to be a question of law in its rulings in the *Kordel* and *Urbuteit* cases, *supra*. In the instant case, the Court of Appeals failed to apply the definition of labeling laid down by this Court, and instead created two different definitions for this same statutory term varying with the section of the Statute in which it appears.

On page 10 of its brief, the Government first attempts to argue that the term "labeling" has not been given different meanings. The Government states that documents which accompany some articles may be false as to those articles even though they are obviously not false as to other articles which they do not accompany. The Government uses the word *accompany* in its literal sense, as a physical concept, rather than as a statutory word of art. Furthermore, this statement is inconsistent with the law laid down by this Court in *Kordel*, *supra*, where this Court held that there is no need for a physical accompanying or presence at the same point of sale so long as they are part of the same integrated distribution program.

It is respectfully submitted that if the Government's argument is correct, then the Government's case must fall by applying its own desired rule of law. The stipulated evidence in this case demonstrates that the claims for the product were not made at the stores, but only at the

lecture halls. The only possible manner by which the Government can establish the first prerequisite for its case, is to apply the claims made in the lectures, at the lecture hall, to the shipment initiated in Massachusetts, which went to both the store and the lecture hall. The only theory whereby said lectures can be applied back to the products at the time of shipment, would be that the lectures were part of the integrated distribution program. To the very same extent that the lectures were part of the integrated distribution program, so too, were the class notes, which were displayed, distributed and available for distribution at those very same lectures together with the products at the lecture hall. The class notes were, therefore, as much a part of the integrated distribution program as the lectures and co-extensive therewith. If the Government contends that we must draw a sharp line of separation between the products shipped from Massachusetts which went to the store and the products which went to the lecture hall, then the same separation must be made for the claims which were made for the products in the lecture hall and which were not made at the store. The Government's contention is self-contradictory and contrary to the decisions of this Court. It is, furthermore, immaterial that an individual received the class notes at the lecture hall and then bought the product at the store. There is no requirement that the product and the literature be together at the same place either physically or in point of time, *Kordel* v. *United States*, *supra*.

On pages 10 and 11 of its brief, the Government attempts to discuss the legal definition of the term labeling applicable herein. It discusses various criteria which it claims are required in order for literature to constitute labeling under the Act. These criteria are contrary to and inconsistent with the definition of the term labeling

heretofore laid down by this Court in *Kordel* and *Urbuteit*, *supra*.

Thus, on page 11 of its brief, it argues that the documents must not be "far removed from the point of sale", and again it states that the labeling material must be "closely enough associated with the drug at the point of its sale". These requirements are precisely the kind of requirements which have been held to be unnecessary in order for literature to accompany a product so as to constitute labeling under the Statute, *Kordel* and *Urbuteit*, *supra*.

The Government further injects on pages 10 and 11 of its discussion of the legal issue herein, the additional word adequate in front of the word labeling. The term in the Statute is not *adequate labeling*, but rather the term *labeling*.

Literature either is labeling under the law or it is not labeling. The legal determination relative thereto has nothing whatsoever to do with any question of adequacy. The issue is whether the literature is labeling, and if so, whether it contains the names of the diseases charged in the information to be missing therefrom. These are two separate questions as discussed in the petition.

The Government comments in the last paragraph on page 11 of its brief, that the requirements can be readily met by "honest enterprise" * by including the promotional material at the point of sale. The question herein is not whether certain requirements can be met. The question is rather as to the requirements which are in fact set forth in the Food, Drug and Cosmetic Act, and the rulings of

* There is no question herein as to so called honest enterprise. There is no charge in the information that any false or misleading claims have been made for the products.

this Court as to such requirements. This Court has heretofore clearly ruled that literature constitutes labeling for a product even though it is not present at the point of sale or physically proximate to the product. If the Government desires to change the requirements of the Act, then such changes should be made by legislative action.

Respectfully submitted,

MILTON A. BASS,
SOLOMON H. FRIEND,
Counsel for Petitioners.

January 1963.